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Nos. 96-728, 96-761

IN THE SUPREME COURT OF THE UNITED STATES

October Term, 1996

DAVID A. KESSLER, M.D ET AL.,
ConditionalCross-Petitioners,

v.

ORGANON, INC., ET AL.,
Respondents.

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION
Conditional Cross-Petitioner,

v.

BRACCO DIGNOSTICS INC., ET AL.,
Respondents.

On Conditional Cross-Petitions for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF RESPONDENTS MERCK & CO., INC., MSD TECHNOLOGY, L.P. and SCHERING CORPORATION IN OPPOSITION

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QUESTION PRESENTED

In 1984, Congress enacted the Hatch-Waxman Act. One part of this act, codified at 35 U.S.C. § 156, states that any patent covering a drug whose marketing is delayed because of regulatory review by the Food and Drug Administration shall receive patent term restoration to compensate for part of that regulatory delay.

In 1994, in a transitional provision in the Uruguay Round Agreements Act, 35 U.S.C. § 154(c)(1), Congress mandated that the term of any patent in force on June 8, 1995, or resulting from an application filed prior to that date, shall be the greater of 20 years from filing of the patent application or 17 years from the grant of the patent, subject to any terminal disclaimer.

The question presented by the conditional cross-petitioners in this case is whether the Court of Appeals for the Federal Circuit erred when it determined that the patent of a drug whose marketing was delayed due to FDA regulatory

review was entitled to the term of 20 years from filing of the patent application mandated by the URAA together with the patent term restoration period authorized by the Hatch-Waxman Act, subject only to the restrictions on term restoration established by the Hatch-Waxman Act.

LIST OF PARTIES

This Opposition to Petitions for Writ of Certiorari is filed on behalf of Merck & Co., Inc., MSD Technology, L.P. and Schering Corporation. The parent company, non-wholly owned subsidiaries, and affiliates of Merck & Co. that have issued shares to the public are:

Banyu Pharmaceutical Co., Limited
Banyu ASC Co., Ltd.
Nippon Merck Banyu Co.Ltd.
Prodome Quimica e Farmacaeutica Ltda.
Kronans Droghandel AB
Kiineiesto Oy Irmelinpesa
Comnet Corporation

MSD Technology, L.P. is a limited partnership, comprised of four partners, three of which are wholly-owned subsidiaries of Merck & Co., Inc. The fourth partnership interest in MSD Technology, L.P. is held by Abbey National Treasury Services, P.L.C.

The parent company, non-wholly owned subsidiaries, and affiliates of Schering Corporation that have issued shares to the public are: Schering-Plough Corporation.

Other parties to the proceedings in the United States Court of Appeals for the Federal Circuit were: Bracco Diagnostics Inc. and Bracco International B.V.; Hoffmann-La Roche Inc. and Syntex (U.S.A.) Inc.; Organon, Inc.; David A. Kessler, M.D., Commissioner of Food and Drugs; Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks; and the Generic Pharmaceutical Industry Association.

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STATUTES INVOLVED

The statutory issues raised by the conditional cross-petitioners in 96-728 and 96-761 arise under the Drug, Price Competition, and Patent Term Restoration Act (the "Hatch-Waxman Act"), codified in relevant part at 35 U.S.C. §§ 156 (a) and (e).

STATEMENT OF THE CASE

The relevant facts and the proceedings below are set forth in the brief in opposition of respondents Merck & Co., Inc., MSD Technology, L.P (together "Merck") and Schering Corporation ("Schering") filed in 96-562 and 96-575.

REASONS FOR DENYING THE WRIT

These cross-petitions for writ of certiorari are conditional on the grant of the petitions in 96-562 and 96-575. The reasons for denying the petitions in those two cases are discussed at some length in the brief in opposition of respondents Merck and Schering. *See* Merck/Schering Opp. at 8-15. Additional grounds for denial are presented by the

conditional cross-petitioners themselves in their oppositions to those two petitions. *See* Fed. Opp. at 9-15; GPIA Opp. at 4-6.

To summarize, the petitions in 96-562 and 96-575 should be denied because they do not present issues of general importance and do not concern a conflict with the decisions of this Court or of any court of appeals. At least one of the arguments raised in 96-562 is not properly presented for review. Moreover, the case in 96-562 is moot.

Even if certiorari were granted in 96-562 or 96-575, however, the conditional cross-petitions should be denied. In addition to the fact that the conditional cross-petitioners themselves acknowledge that this case does not present any issue of general importance -- a point highlighted by the decision of the Solicitor General not to seek certiorari in the normal course -- cross-petitioners cannot show a substantial basis for believing that the court below erred in its interpretation of the Hatch-Waxman Act.

The interpretation of the Hatch-Waxman Act adopted by the court below is the only reading faithful to the language, history, and structure of the Hatch-Waxman Act. Federal cross-petitioners are incorrect in their assertion that the court below erred by not deferring to the "Final Determination" of the PTO, which claimed to interpret provisions of the Hatch-Waxman Act, as this is not a case where *Chevron* deference applies. Moreover, the interpretation of the Hatch-Waxman Act urged by federal cross-petitioners cannot be reconciled with the statutory language, history, and structure of the statute. Nor is there any better support in the statute for the different position taken by conditional cross-petitioner Generic Pharmaceutical Industry Association ("GPIA"), which correctly rejects the position taken by the federal cross-petitioner. *See* 96-761 Cross-Pet. at 6-7.

1. To secure review by this Court in the absence of a conflict among circuits,[1/] conditional cross-petitioners must demonstrate both that there is a substantial basis for believing that the court below erred in its construction of the governing statute and that the issue has substantive importance. *See* Sup. Ct. R. 10(c). The cross-petitioners are unable to meet this standard.

As the conditional cross-petitioners forthrightly acknowledge, this case does not present an issue of general importance. Rather, the case concerns only a transitional provision of highly attenuated significance. *See* 96-728 Cross-Pet. at 3; *see also* 96-761 Cross. Pet. at 7. Even that limited significance is being continually eroded by time, as additional patents subject to the transitional rules of 35 U.S.C. § 154(c)(1) expire. For example, as the cross-petitioners

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[1/] Cross-petitioners do not claim that this case presents a circuit split. Moreover, because the determination of issues arising under 35 U.S.C. § 156 are within the exclusive jurisdiction of the Federal Circuit under 28 U.S.C. §1295(a)(1), there could not be a conflict among the circuits on the issues presented here.

pointed out in their briefs in opposition in 96-562 and 96-575, the passage of time has already made the case in 96-562 moot. *See* Fed. Opp. at 9; GPIA Opp. at 2.

2. Nor can the conditional cross-petitioners show a substantial basis for believing that the court below erred in its construction of the governing statute. None of the cross-petitioners challenge the Federal Circuit's holding that all of the patents in issue were in force on June 8, 1995, *see* 35 U.S.C. § 154(c)(1), which is the only issue decided below that required an interpretation of the Uruguay Round Agreements Act ("URAA"). Thus, the only issue of law raised by the cross-petitioners is whether the Federal Circuit correctly interpreted the Hatch-Waxman Act. On that latter point, the holding of the Federal Circuit relies on an interpretation of the Hatch-Waxman Act that, unlike those proposed by the conditional cross-petitioners, conforms with the mandatory language of the statute and is equally supported by the history and structure of the Act.

In the URAA, Congress changed the terms of patents from 17 years from grant of the patent to 20 years from filing of the patent application. Transitional provisions incorporated in the URAA require that the term of patents in force on June 8, 1995, or that result from applications filed before that date "shall be the greater of" 17 years from grant or 20 years from filing. 35 U.S.C. § 154(c)(1). (Emphasis added). The wording of the URAA is unequivocal and mandates a 20-year-from-filing term in all cases where the patent was in force on June 8, 1995, and the 20-year term exceeds the term of 17 years from grant.[2/]

The Hatch-Waxman Act, enacted a decade earlier than the URAA, authorizes patent term restoration as partial compensation for the loss of effective patent life[3/] suffered by products, such as drugs, that are subject to FDA pre-

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[2/] As this Court has repeatedly held, Congress's use of the word "shall" establishes an inflexible requirement. *See, e.g., Fogarty* v. *Fantasy, Inc.*, 510 U.S. 524, n.11 (1994).

[3/] The term "effective patent life" refers to the period between FDA marketing approval for the product and the expiration of patent protection.

marketing regulatory review.[4/] 35 U.S.C. § 156. Section 156(a) states that eligible patents "shall be extended in accordance with this section from the original expiration date of the patent." (Emphasis added.) The Federal Circuit held that the term "'original expiration date' means no more than that the expiration date has not been extended under section 156(e)(1)." *See* 96-562 Pet. App. at 17a. The Federal Circuit's interpretation of this phrase is based directly on the language Congress added to Section 156(a)(2) when it enacted the URAA and is unambiguously supported by the legislative history of the Hatch-Waxman Act and the structure of 35 U.S.C. § 156.

When the Hatch-Waxman Act added Section 156 to Title 35, the term of patents, including those subject to Hatch-Waxman term restoration, was 17 years from grant. No

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[4/] The Hatch-Waxman patent term restoration periods do not compensate fully for the time lost in regulatory review, but merely "ameliorate the loss incurred when patent terms tick away while the patented product is awaiting [FDA] regulatory approval for marketing." *Unimed, Inc.* v. *Quigg*, 888 F.2d 826, 829, 12 U.S.P.Q.2d (BNA) 1644, 1647 (Fed. Cir. 1989).

extensions of that term were available for any patents other than pharmaceutical patents covering products whose marketing had been delayed by the FDA's regulatory processes. The phrase "original expiration date" in Section 156(a) simply served to distinguish the expiration date of a patent prior to consideration of the Hatch-Waxman Act from the expiration date inclusive of the Hatch-Waxman term restoration period.

This understanding is directly confirmed in a 1982 letter from the congressional draftsman of the phrase, then-Congressman Tom Railsback, to Bruce A. Lehman[5/] explaining why the phrase had been inserted into legislation that later became Section 156(a). *See* 96-562 Pet. App. at 15a-16a. This letter makes it clear that "original expiration date" refers to the date on which the patent would have

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5/ At the time, Congressman Railsback was the ranking minority member of the Subcommittee on Courts, Civil Liberties, and the Administration of Justice, which had substantive jurisdiction of the matter, and Mr. Lehman was counsel to the subcommittee. Mr. Lehman is now Commissioner of Patents and Trademarks and one of the cross-petitioners.

expired if not for the addition of a Hatch-Waxman restoration period.

> The insertion of 'from the original expiration date of the patent' . . . makes specific what was intended, namely, that the maximum extension . . . must be calculated from the original date of the patent. Thus, 2 five-year regulatory review periods for 2 different products under the same patent will result in only one extension from the original patent expiration date.

The single change that the URAA made in the Hatch-Waxman Act provides further direct support for the Federal Circuit's decision. The URAA amended 35 U.S.C. § 156(a)(2) by adding the underscored phrase to provide that a Hatch-Waxman extension may be granted as long as "the term of the patent has never been extended under subsection (e)(1) of this section." This change was needed because other provisions of the URAA for the first time[6/] permitted patent

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[6/] Prior to the enactment of the Hatch-Waxman Act in 1984, Congress added Sections 155 and 155A of the Patent Act, which provide statutory term extensions for a limited number of patents covering the food additive aspartame (Section 155) and the drug forane (Section 155A). *See United Sweetener USA, Inc.* v. *Nutrasweet Co.*, 760 F. Supp. 400, 419 (D. Del. 1991) (aspartame); 129 Cong. Rec. S. 6313 (daily ed. May 19, 1983) (statement of Mr. East) (forane).

term extensions for reasons other than FDA regulatory delay.[7/]

This amendment explicitly demonstrates the Congressional expectation that a patent term enlarged by the URAA could also benefit from Hatch-Waxman restoration under 35 U.S.C. § 156. The Hatch-Waxman restoration period of such a patent would be calculated from its "original expiration date," *i.e.*, the date the patent would expire if it were not extended pursuant to 35 U.S.C. § 156(e)(1). Thus, the language and structure of Section 156(e) as amended by the URAA also compels the Federal Circuit's interpretation of "original expiration date" (*see supra* p. 8) and its conclusion that respondents Merck and Schering are entitled to add Hatch-Waxman term restoration periods to the URAA-mandated 20-years-from-filing terms of their patents in suit,

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7/ The URAA authorized patent term extensions under 35 U.S.C. § 154(b)(1) to compensate for the loss of effective patent life resulting from interference delay and secrecy orders and authorized patent term extension under 35 U.S.C. § 154(b)(2) to compensate for delays due to appellate review of an adverse determination of patentability.

subject only to any applicable restrictions contained within the Hatch-Waxman Act itself.

3. The primary claim of the federal conditional cross-petitioners is that the Federal Circuit should have deferred to the interpretation of the statute by the PTO under *Chevron, U.S.A.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984). 96-562 Pet. App. at 14a.

This is plainly not a case where *Chevron* deference is appropriate. This case does not involve any issue relating to the PTO's particular expertise in an area in which Congress has granted it discretionary powers.[8/] *Compare Babbitt* v. *Sweet Home Chapter of Communities for a Great Oregon,* 115 S.Ct. 2407, 2418 (1995) (deference granted to agency with "broad discretion" in circumstances requiring "an expertise and attention to detail that exceeds the normal province of

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[8/] This case thus stands in sharp contrast to *Smiley* v. *Citibank (South Dakota) N.A.,* 116 S.Ct. 1730 (1996), for example, which concerned an interpretation of the banking laws by the Comptroller of the Currency, who "is charged with the enforcement of banking laws *to an extent that warrants the invocation of* [deference]." *Smiley,* 116 S.Ct. at 1733 (citations and internal quotation marks omitted) (emphasis added).

Congress"). This case does not involve the PTO's special expertise in scientific matters. Rather, it concerns the interpretation of the Patent Act. The federal judiciary has for two centuries been and remains the final arbiter of the meaning of the patent statue. The Federal Circuit has plainly been correct in repeatedly holding that no deference is due to the PTO's interpretations of the Patent Act. *See, e.g., Hoechst Aktiengesellschaft* v. *Quigg,* 917 F.2d 522, 526 (Fed. Cir. 1990) (no deference granted to PTO interpretation of ambiguous statutory language); *Glaxo Operations U.K., Ltd.* v. *Quigg,* 894 F.2d 392 (Fed. Cir. 1990) (in cases involving dissection of statutory language, courts are equally skilled in making interpretations).[2/]

[2/] It is worth noting that the Solicitor General did not seek a writ of certiorari in either of these cases. This is consistent with the position taken by the Solicitor General in the present case in opposing the petitions for certiorari in 96-562 and 96-575 and in other cases where the Federal Circuit refused to defer to the PTO's interpretation of the Hatch-Waxman Act. *See Ethicon, Inc.* v. *Quigg,* 849 F.2d 1422 (Fed. Cir. 1988) (certiorari not sought).

It is indicative of the PTO's limited role in interpreting the patent statute that Congress has granted the PTO only very limited rulemaking authority. As the Federal Circuit has held, the broadest of the PTO's rulemaking powers, found in 35 U.S.C. § 6(a), authorizes the Commissioner to promulgate regulations only "for the conduct of proceedings in the [PTO]," and does not grant authority to issue substantive rules. *See Ethicon, Inc.* v. *Quigg*, 849 F.2d 1422, 1425 (Fed. Cir. 1988). Accordingly, the PTO's statutory interpretation "cannot possibly have the force and effect of law." *Animal Legal Defense Fund* v. *Quigg,* 932 F.2d 920, 930, U.S.P.Q.2d at 1686 (Fed. Cir. 1991).

The PTO particularly lacks substantive rulemaking power over the Hatch-Waxman Act, for its role in the administration of the statute is purely clerical. The PTO receives applications for patent term restoration under the Hatch-Waxman Act, but is required to notify the FDA immediately. 35 U.S.C. § 156(d)(2)(A). The FDA

determines the period of regulatory delay that occurred and is authorized to hold a hearing and to resolve disputed issues as appropriate. 35 U.S.C. § 156(d)(2)(B). The PTO's role is limited to making certain arithmetic calculations after being informed of the length of the regulatory delay by the FDA.[10/] The calculation of the patent term restoration period is a purely mechanical exercise, involving addition and subtraction but no discretion.

4. In this case, it would be particularly inappropriate for the judiciary to defer to the PTO's interpretation of the Hatch-Waxman Act in light of the PTO's substantive flip-flop on the issue presented in this case. On

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[10/] The PTO calculates the length of the patent term restoration period by adding half the number of days that the patented product or method underwent clinical trials to the number of days the subsequently filed "New Drug Application" was pending before the FDA, subject to two limitations. First, the restoration period cannot exceed five years for patents issued subsequent to the enactment of the Hatch-Waxman Act; patents issued prior to the enactment of the Hatch-Waxman period generally are limited to a two-year extension. 35 U.S.C. § 156(g)(6). *Cf. Hoechst Aktiengesellschaft* v. *Quigg*, 917 F.2d 522 (Fed. Cir. 1990) (patent term restoration not limited by Section 156(g)). Second, the effective patent life cannot exceed 14 years. 35 U.S.C. § 156(c)(3).

March 27, 1995, after extensive consideration, the PTO published a "Proposed Determination" concerning the application of the URAA patent term transitional provision to patents in force on June 8, 1995, that qualified for term restoration under the Hatch-Waxman Act. 60 Fed. Reg. 15748 (Mar. 27, 1995). In this statement, the PTO expressed the view that the terms of such patents should be computed by adding the Hatch-Waxman restoration period to the end of the 20-year URAA term.

On June 7, 1995, the PTO completely reversed the position it had articulated ten weeks earlier and issued a so-called "Final Determination" announcing a revised view that holders of patents in force on June 8, 1995, and subject to Hatch-Waxman patent term restoration, "are entitled" to the longer term of either "(a) 17 years from grant, supplemented by the period of extension [under the Hatch-Waxman Act]," or "(b) 20 years from their relevant filing date," without any Hatch-Waxman restoration period. 60 Fed. Reg. 30069 (June

7, 1995). The PTO cited no new information that justified this about-face. *Id.* The PTO simply changed its mind.

5. Even if the PTO's interpretations of the Hatch-Waxman Act were generally entitled to deference under *Chevron*, the PTO's interpretation of "original expiration date" deserves no such deference because it cannot be reconciled with the language, history, and structure of the statute. The federal conditional cross-petitioners cannot explain away the Railsback letter, so they attempt to dismiss it as "superfluous."[11/] *See* 96-928 Cross. Pet. at 10. Nor can the federal cross-petitioners square the PTO's position with the sole amendment the URAA made to the Hatch-Waxman Act. If "original expiration date" meant the expiration date anticipated on the day the patent was granted, a patent extended under provisions other than 35 U.S.C. § 156(e)(1),

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11/ Recent amendments to the Hatch-Waxman Act, however, do not affect the historical import of the Railsback letter which, as the Federal Circuit recognized, helps explain the meaning of the phrase "from the original expiration date of the patent."

such as Section 154(b) as amended by the URAA, would be barred from also receiving Hatch-Waxman term restoration. Such an outcome is clearly contrary to the language of 35 U.S.C. § 156(a)(2).

Federal conditional cross-petitioners also claim that permitting the addition of Hatch-Waxman restoration periods to the URAA mandated 20-years-from-filing term could result in the violation of 35 U.S.C. § 156(c)(3), which places a 14-year limit on the effective patent life of a patent that has received Hatch-Waxman term restoration. *See* 96-728 Cross-Pet. at 10-11. They disregard the fact that the 14-year rule is one of the limitations on patent term restoration that is directly incorporated in the Hatch-Waxman Act and that the Federal Circuit held to be applicable to patents whose terms are enlarged by the transitional provisions of Section 154(c)(1).[12/] As the Federal Circuit recognized, nothing

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12/ The district court and Federal Circuit both held that the term of Merck's U.S. Patent No. 4,283,408 must be calculated so as not to exceed (continued...)

more than an arithmetical calculation is required to conform with the 14-year rule of section 156(c)(3). *See* 96-562 Pet. App. at 17a-18a.[13/]

6. The wholly distinct interpretation of the Hatch-Waxman Act urged by conditional cross-petitioner GPIA similarly lacks foundation in the statutory language. GPIA concurs with the Federal Circuit's interpretation of "original expiration date", but argues that permitting a Hatch-Waxman restoration period that was granted prior to June 8, 1995, to be added on to a URAA-mandated 20-years-from-application term would constitute a second application of a restoration

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[12/](...continued)
the 14-year limit on effective patent life set forth in 35 U.S.C. 156(c)(3). *See* 96-562 Pet. App. at 18a-19a; 96-575 Pet. App. at 33a.

[13/] Federal conditional cross-petitioners also raise the specter of the "problem of fitting together the different limitations on remedies during successive extensions," and suggest that the only way to address this problem is to prohibit in all cases the addition of a Hatch-Waxman term restoration period to a URAA-mandated 20-year-from-filing term. *See* 96-728 Cross-Pet. at 11, n. 9. Thus far, no reported case presenting such a problem has arisen, supporting the Federal Circuit's conclusions that "this problem is more illusory than real," and that "the majority of patents should not be denied extensions because of a mere possibility that special problems may arise in a few instances." *See* 96-562 Pet. App. at 19a-20a.

period in violation of Section 156(a).[14/] This argument, which was considered and rejected by the Federal Circuit, has no basis in the language of the statute and suffers from the additional flaw that it assumes that the URAA *sub silentio* withdrew previously certified Hatch-Waxman term restoration periods from pharmaceutical patents assigned the 20-years-from-filing term by Section 154(c)(1). If the URAA had been intended to affect patent term restorations in such a manner, Congress would have to have explicitly amended the language of Section 154 or Section 156. *See, e.g., Bristol-Myers Squibb* v. *Royce Laboratories,* 69 F.3d 1130, 1136 (Fed Cir. 1995), *cert. denied.,* 116 S.Ct. 754 (1996) (had Congress intended URAA to change Hatch-Waxman, it would have done so explicitly).

[14/] GPIA appears to call into question the mandatory nature of the transitional provision of the URAA, Section 154(c)(1), by claiming that the statute provides each patent "the option" of applying the 20-year-from-application patent term. 96-761 Cross. Pet. at 9 (emphasis added). As discussed above, Section 154(c)(1) is clearly mandatory. *See supra* p. 7.

CONCLUSION

The conditional cross-petitions in 96-728 and 96-761 for a writ of certiorari should be denied.

Respectfully submitted,

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